

NATIONAL GRAIN TRADE COUNCIL
&
TRANSPORTATION, ELEVATOR, AND GRAIN MERCHANTS ASSOCIATION

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December 22, 2003

Dockets Management (HRA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Prior Notice of Imported Food Under the Public Health Security and
Bioterrorism Preparedness and Response Act of 2002; Docket No. 02N-0278; 68
Fed. Reg. 197 (October 10, 2003)

Dear Sir or Madam:

These comments are submitted on behalf of the members of the National Grain Trade Council (NGTC) and the Transportation, Elevator and Grain Merchants Association (TEGMA). NGTC is a national trade association established to advocate and defend open and competitive markets for the distribution of agricultural commodities. NGTC members include grain exchanges, boards of trade, and national grain marketing organizations as well as agribusiness companies handling and processing 80-85% of all U.S. grain exports. TEGMA members represent a broad cross-section of the freight transportation industry, including railroads, barge companies, port authorities and terminal elevators linked by the shipment of grain from the farm to customers all over the world.

NGTC and TEGMA welcome the opportunity to comment on the U.S. Food and Drug Administration's (FDA) interim final rule to implement Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). Section 307 requires FDA to issue regulations requiring the submission of notice in advance of any importation of food into the United States. NGTC and TEGMA support necessary and appropriate measures to combat bioterrorism and respect the agency's efforts to implement the various provisions of the Bioterrorism Act as directed by Congress. However, it is critical that such measures do not interfere with open, competitive commerce in agriculture or compromise the efficiency, competition and safety in the handling and transportation of North American grain and grain products. Specifically, NGTC and TEGMA believe the published interim final rule fails to incorporate the expediency and unpredictability of rail and land shipping and thus creates additional complications, which will undermine its effectiveness in protecting national security.

NGTC and TEGMA take issue with the rigidity of the prior notice regulations. All shipments of food imported or offered for import into the U.S. must be submitted and confirmed electronically as complete by FDA for review no less than four hours for food arriving by land/rail and two hours for food arriving by land/road. With regard to daily shipments crossing the U.S. borders, it is impossible to pinpoint the timetables of truck shipments to a two-hour window or predict the railroads' adherence to schedule patterns within a four-hour window. If either mode is delayed or redirected, new notice documentation is required electronically, preventing laborers from moving their shipments undisturbed to their destination. If shipments are loaded at the border, railcars and trucks will have to wait their full notification time period before crossing, removing any expediency provided by the industry. Also, railroads are fixed conveyances. If schedules are disrupted, railcars cannot be parked "out of the way,"

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but will be stopped on the same lines used for all traffic. Delays and backlogs at the border will only cause increased national security concerns, as shipments are forced to wait without 24-hour supervision instead of smoothly crossing to the point of delivery.

Furthermore, reporting "time frames" should not favor one mode over another. If advance notice must be given, time frames should be structured equally such that trucks and rail face similar requirements. NGTC and TEGMA recommend that prior notice regulations for both land/rail and land/road be lowered to one hour. This will increase competition between modes rather than granting one the advantage gained by a shorter reporting time frame.

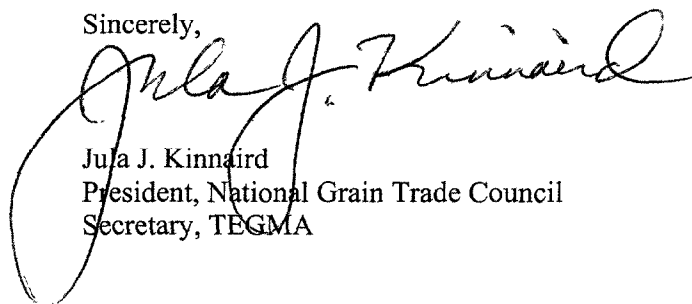
Another critical component is coordination between FDA and U.S. Customs & Border Protection (CBP). FDA reporting time frames and notification systems must coincide with those applied by CBP. Currently, the two agencies have released prior notice regulations that do not correspond. Mandating that shippers must register in advance with both agencies at different times, will inevitably result in a bureaucratic tangle that will increase backlog and confusion at border crossings, raising the level of chaos and insecurity beyond that which strained border officials can competently handle. NGTC and TEGMA urge FDA and CBP to synchronize their prior notice requirements in order to avoid any uncertainty resulting from multiple notification procedures.

NGTC and TEGMA also are concerned with §1.281, Proposed as §1.288, "What Information Must Be in a Prior Notice?," which states that the submitter may provide the grower for an article of food that is in its natural state, unless unknown, and the consolidator. Although this information request is voluntary, we want to assure that it does not become mandatory in the final published rule. Such a requirement is virtually impossible due to the realities of our grain handling system. Once the grain is commingled at the country elevator, it is impossible to discern the individual grower from which each kernel, bean or seed originated. Grain is deposited in 100,000 bushel bins and from there transferred to railcars or trucks to be transported. Once the grain enters this transfer process, it is unreasonable to require notification of which producers contributed to which shipments. This notification must remain voluntary so as not to further impede the cross-border shipments of grain.

Shippers and carriers have worked expeditiously to develop a safe and efficient transportation system. The agencies, by implementing this rule of the Bioterrorism Act as published, will inevitably impede trade at our borders. This will only create a domino effect as railcars are delayed in arriving at the country elevators, the elevators are delayed in loading grain from trucks and so on down to the farm. We urge the agencies to work more closely with industry to implement programs which do not cause further harm to our nation's transportation and agricultural systems as part of efforts to protect national security.

We hope that you will consider the foregoing recommendations as you develop final regulations to implement Section 307 of the Bioterrorism Act. If we may provide any additional information in this regard, or if we may be of assistance in any other way, please do not hesitate to contact us.

Sincerely,

A large, stylized handwritten signature in black ink, which appears to read "Julia J. Kinnaird". The signature is written over the typed name and title.

Julia J. Kinnaird
President, National Grain Trade Council
Secretary, TEGMA